JUL 11 2008

K973555 (P. 1 of 2)

510(K) SUMMARY
[21 CFR 807.92]

Submitter:	Medicool, Inc. 20460 Gramercy Place Torrance, CA 90501 (800) 433-2469
Contact Person:	Michael Mahon
Date prepared:	November 12, 2007
Date last revised:	May16, 2008
Proprietary Device Name:	Insulin Protector™
Comparable Device(s):	N/A

I. Device Description

The Medicool Insulin Protector™ is a capsule-like portable container designed to transport insulin in a temperature controlled environment and protect it from environmental shock and other trauma. The Insulin Protector™ essentially consists of three main parts: the cooling tray, the foam insulation, and the outer casing.

The cooling tray is a hollow-walled plastic container which has a cavity formed therein. The cooling tray is filled with water, which can be refrigerated in an ordinary household refrigerator. The cavity in the cooling tray receives up to two bottles of liquid insulin. The bottom and sides of the cavity include a plurality of ribbed members to prevent direct contact between the insulin bottles and the side walls of the cooling tray.

The cooling tray fits inside the foam insulation snuggly to minimize heat transfer and loss, thus effectively stabilizing the inside temperature. This sleeve insulating foam is manufactured by Marko Foam and referenced as BI-99. The foam is flexible and helps provide protection from shock and trauma to the insulin bottles being stored in the cooling tray. The foam has cavities in both the top and bottom sections to receive the removable cooling tray. When the cooling tray is inserted into the cavity, a portion of the cooling tray extends above the surface of the foam. However, when the top section is closed, the cooling tray extends into the cavity of the top foam.

The foam insulation containing the cooling tray fits snuggly inside the outer casing. The outer casing is stitched together using Cordura material, which is quality fabric known for its durability and resistance to abrasion. A zipper is used to open and close the main compartment that holds the foam insulation and the cooling tray. On the outside of the bag are two smaller pockets that close using Velcro; these pockets are designed to hold accessories, such as syringes, alcohol wipes, swabs, etc.

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II. Statement of Intended Use

The Insulin Protector is designed to protect bottles of insulin while keeping them cool. It is not designed to carry or store human organs, fluids, or tissue in any form.

This device's target population is people who require insulin.

III. Summary of Similar Technological Characteristics

Insucozi (K072174)

IV. Discussion and Conclusions of Submitted Testing

In the durability experiment (Nonclinical Test: Verification Testing Of Cooling Times For Medicool Insulin Protector® Case Determining Whether a Medicool Insulin Protector® Protects Inside Contents Under Physical Stress), the Insulin Protector's ability to protect the bottles of insulin (which was made of glass that could potentially shatter) was challenged through a series of intensive abusive trials using various insulin bottle types. After several trials using different methods of generating shock, it was concluded that the device resisted damage and preserved the contents inside perfectly.

In the insulin cooling experiment (Nonclinical Test: Verification Testing Of Cooling Times For Medicool Insulin Protector® case), the Insulin Protector®'s ability to keep insulin below the manufactures safe limit was 12 hours. Our test was conducted with Insulin vials in the only 2 variations that we have seen in our 22 years in business, a 10mL US vial and a 10mL EU vial.

In conclusion, the Insulin Protector™ performs adequately for what it is designed and marketed to do.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2008

Mr. Michael Mahon
Medicool, Incorporated
20460 Gramercy Place
Torrance, California 90501

Re: K073555
Trade/Device Name: Insulin Protector
Regulation Number: 21 CFR 890.5050
Regulation Name: Daily Activity Assist Device
Regulatory Class: I
Product Code: IQG
Dated: May 16, 2008
Received: May 30, 2008

Dear Mr. Mahon:

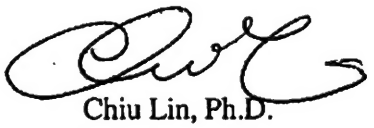
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-*[See Below For Phone Numbers]*. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073555

Device Name: INSULIN PROTECTOR

Indications For Use:

The Insulin Protector is designed to protect bottles of insulin while keeping them cool. It is not designed to carry or store human organs, fluids, or tissue in any form.

This device's target population is people who require insulin.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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